Alert Nutrition, LLC

January 14, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

FEB 16

Gentlemen:

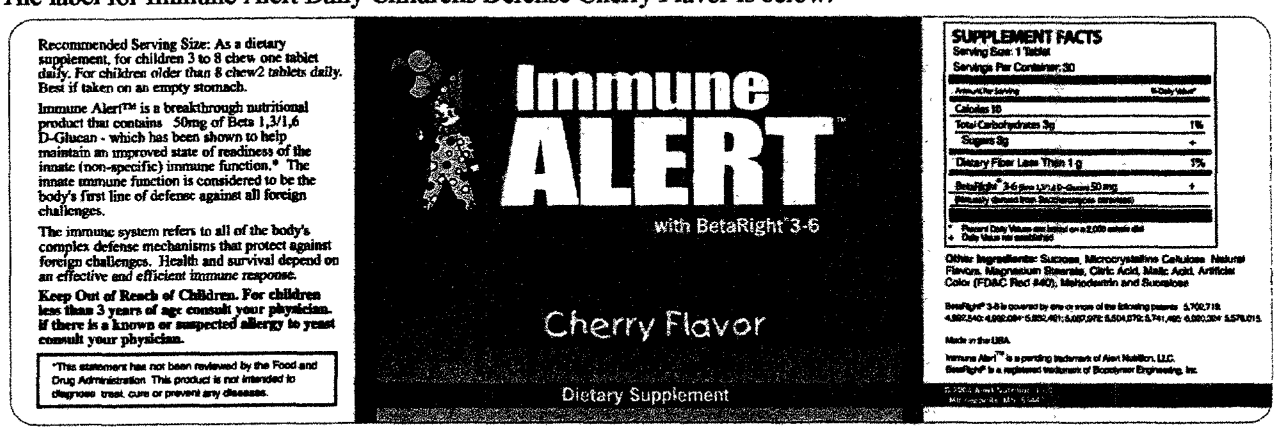
Complying with the requirements of 21CFR101.93, I am advising FDA of the initiation of marketing of **Immune Alert™ Childrens Daily Defense Cherry Flavor** by Alert Nutrition, LLC. Initial marketing occurred during the week of January 9, 2005.

The distributor's address is Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391. Alert Nutrition's phone number is (763) 473-0096.

The label includes the Structure/Function claim "Immune Alert™ is a breakthrough nutritional product that contains 50 mg of Beta Glucan – which has been shown to help maintain an improved state of readiness of the innate (non-specific) immune function.*" The label also includes the FDA disclaimer "*This statement has not been reviewed by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases."

The Structure/Function claim is based upon the research findings of laboratory and clinical investigations on beta glucan. Immune Alert Daily Defense Cherry Flavor contains patented BetaRight® 3-6 of beta 1,3/1,6 glucan extracted from food-grade Baker's yeast (Saccharomyces cerevisiae), a FDA- approved food ingredient (21CFR170.30).

The label for Immune Alert Daily Childrens Defense Cherry Flavor is below:



Regards,

Jerome Licari, Ph.D.
President
Alert Nutrition, LLC.

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CC: Judy E. Heisick, FDA; Minneapolis District

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